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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,122	08/18/2006	Sang Min Kim	87914.00002	1310

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PATENT DEPARTMENT
ONE MARITIME PLAZA, SUITE 300
SAN FRANCISCO, CA 94111-3492

EXAMINER	
BROWE, DAVID	
ART UNIT	PAPER NUMBER
4131	

MAIL DATE	DELIVERY MODE
04/21/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/598,122	KIM ET AL.	
	Examiner	Art Unit	
	DAVID M. BROWE	4131	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *January 29, 2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

I. Arrangement

Cross reference should be made to related applications (for example, PCT/KR2006/001598) in the first sentence(s) of the specification after the title, or in an Application Data Sheet (ADS). Reference must include identification by international application number and international filing date, and indicate the relationship of the applications.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
    (1) Field of the Invention.
    (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.

(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact discs.

II. Minor Informalities

The disclosure is objected to because of the following spelling and grammar informalities: The word additionally is misspelled as "addtionaly" (Pg. 9, ln. 14); the word "were" should be in place of the word "was" in the sentence "...and magnesium stearate was then added to..." (Pg. 15, ln. 6); and the word "and" in the sentence "A separation layer *and* was introduced then coated..." (Pg. 16, ln. 4) should be repositioned so that the sentence instead says "A separation layer was introduced *and* then coated...".

Appropriate correction is required.

Abstract

The abstract of the disclosure is objected to because it contains the self-evident clause "The present invention relates to", and also contains the improper grammatical construction "a hydrates or anhydrides". Correction is required. See MPEP § 608.01(b).

Claim Rejections – 35 U.S.C. § 112 2nd Paragraph

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The reference to w/w% fails to clearly specify whether the values are based on weights of high- and low-viscosity HPMC relative to, for example,

the total weight of the paroxetine-containing granules, the total weight of the tablet core, or some other measure.

Claim Rejections - 35 U.S.C. § 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leonard et al., EP 1 382 337 A1, in further view of Conte et al., USP 5,422,123, Chen et al., USP 6,720,003 B2, and Lowey, USP 4,775,535.

Leonard et al. disclose a sustained-release tablet for oral administration having a tablet core comprising paroxetine as pharmaceutically active substance, a support platform (partial separation layer), and an outer enteric coating layer. The tablet core contains paroxetine, preferably as paroxetine hydrochloride hemihydrate (Pg. 3, sec. 0021), formulated as granules, with both high- and low-viscosity hydroxypropylmethylcellulose, and pharmaceutically acceptable excipients. Leonard et al. state that the support platform (partial separation layer) may comprise hydrophilic and/or hydrophobic agents (Pg. 3, sec. 0020, lns. 8-11), and specifically cite Conte et al. (USP 5,422,123) for particularly preferred formulations (Pg. 2, sec. 0019). Conte et al. specify that the following substances can be used to prepare the support platform: water-insoluble polymers such as ethylcellulose, carboxyvinylpolymers (polyvinylacetate), and methacrylates (ammoniomethacrylate copolymer types B); and water-soluble polymers such as hydroxypropylmethylcellulose, methylcellulose, polyvinylpyrrolidone, hydroxypropylcellulose, methacrylates (ammoniomethacrylate copolymer type A), and polyvinylalcohols (Col. 3, lns. 8-19, 36-38). Leonard et al. further state that the enteric coating consists of methacrylate copolymers (Pg. 8, sec. 0045), and that those that benefit most from their formulation are those known to suffer from nausea upon oral administration of an immediate-release product (Pg. 2, sec. 0015). Leonard et al., however, disclose a support platform that only partially encloses the

tablet core and do not specify that the support platform (separation layer) is 1-30 w/w% relative to the tablet core. They also do not disclose the step of further adding low-viscosity hydroxypropylmethylcellulose to the paroxetine-containing granules.

Chen et al. (USP 6,720,003 B2) disclose tablet core compositions of paroxetine hydrochloride (Col. 6, ln. 48) with a water-soluble polymer (Col. 4, lns. 10-17), preferably low-viscosity hydroxypropylmethylcellulose (Col. 7, lns. 42-46), and dried to produce a granulate. The paroxetine-containing granules may then be combined with further low-viscosity hydroxypropylmethylcellulose (Col. 9, lns. 11-13) or other pharmaceutically acceptable excipients Col. 8, lns. 7-9), and pressed into a solid oral dosage form. As shown in Example 1, Table B (Col 11), the paroxetine hydrochloride granules may comprise within from 40-90 w/w% based on the total weight of the tablet core. Chen et al. further disclose that the tablet core may be overcoated with a film-coating in combination with an enteric coating material. The film-coating may consist of hydroxypropylmethylcellulose, methacrylate copolymers, ethylcellulose and other celluloses and derivatives thereof, polyvinylalcohols and the like ((Col 4, lns. 63-67; Col 10, lns. 12-14, 16-20, 22-30, 33-35). These film-coatings, which are understood to be equivalent to a separation layer that completely encloses the tablet core, may comprise within from 0.5% to 30 w/w% based on the weight of the tablet core (Col. 10, lns. 45-50). The enteric coating polymers disclosed by Chen et al. include methacrylate copolymer, hydroxypropylmethylcellulose phthalate, cellulose acetate phthalate, other particular cellulose derivatives, and mixtures thereof. (Col. 10, lns. 25-30)

Lowey (USP 4,775,535) discloses sustained release formulations for unit dosage forms with substantially uniform and comparable bioavailability characteristics (Col. 2, lns. 59-68; Col 3, ln. 1) using hydroxypropylmethylcellulose as the preferred carrier base material (Col. 6, lns. 34-35). Examples II-III (Col. 8) illustrate oral tablet formulations with advantageous sustained-release performance comprising an active agent; low-viscosity hydroxypropylmethylcellulose, comprising within 10-40 w/w% of tablet core and with viscosity within the range from 40-60 cps; high-viscosity hydroxypropylmethylcellulose comprising within 3-30% of tablet core and with viscosity within the range from 3,000 to 14,000 cps; and pharmaceutical excipients.

Formulating enteric coated oral dosage forms with water-soluble and insoluble polymers of the types described is a well established practice in the art (Lowry et al., Col. 1, lns. 52-63). It would have been obvious to one of ordinary skill in the art at the time of the present invention to design a sustained-release tablet in which a separation layer completely enclosed a tablet core based on the teachings of Chen et al., and to incorporate the selected ranges of w/w% proportions for the various tablet ingredients and components as described based on the teachings of Chen et al. and Lowey et al. with reasonable expectation of success in achieving superior sustained-release performance with uniform and comparable bioavailability.

Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID M. BROWE whose telephone number is 571-270-1320. The examiner can normally be reached on Monday-Friday 7:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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